1. Study Information

Protocol Title:

Nd:YAG Laser Photobiomodulation for Neurosensory Recovery Following Bimaxillary Orthognathic Surgery: A Randomised Sham-Controlled Double-Blinded Clinical Trial

Principal Investigator & Contact Details:

DR YONG CHEE WENG
CONSULTANT, DIVISION OF ORAL AND MAXILLOFACIAL SURGERY, NATIONAL UNIVERSITY HOSPITAL (NUH)
9 LOWER KENT RIDGE ROAD, SINGAPORE 119086
PHONE NUMBER: 97872962
Email: DENCWY@NUS.EDU.SG

Study Grant:
Oral Care, Health Innovations and Designs Singapore

2. Purpose of the Research Study

You are invited to participate in a research study. Please read this information sheet carefully before deciding whether to take part. Take your time and feel free to ask any questions. A copy of this form will be given to you to keep.

You are invited because you have recently had jaw surgery (bimaxillary orthognathic surgery) at NUH, and you may be experiencing numbness or altered sensation in your lower lip, chin, or cheek area. This is a common side effect of jaw surgery caused by temporary injury to the nerves in the area. There is no published local data on neurosensory disturbances after orthognathic surgery, thus an estimated data is added in. Post-operative functional sensory loss of the inferior alveolar nerve and infra-orbital nerve is experienced in >90% of patients up to 2 months). At 6 months, ~15% and ~35% of patients still have functional sensory deficits.

This study is being carried out to find out whether a painless low-energy laser light treatment (called photobiomodulation or PBM) applied to the skin over the affected nerve areas can speed up the recovery of sensation after jaw surgery, compared with a sham (inactive) version of the same treatment where no laser energy is delivered.

This study will recruit 36 participants from the Department of Oral and Maxillofacial Surgery, NUH, Singapore. You are one of 36 participants being invited to take part in this study at NUH.

3. What procedures will be followed in this study

If you take part in this study, you will be randomly assigned (like the toss of a coin) to one of two groups: the laser treatment group or the sham (inactive laser) group. Each group has 18 participants. (Total of 36 for both groups).

Neither you nor the person measuring your sensation recovery will know which group you are in. The doctor applying the laser will know, but will not be involved in measuring your recovery. This is done to ensure the results are fair and unbiased.

If you take part in this study, you will be asked to attend 10 clinic visits over 13 months. At each visit, a trained assessor will gently test the feeling in your lower face and cheek using simple painless instruments. You will also complete two short questionnaires.

Your participation in the study will last approximately 13 months from post-surgery. You will receive 6 laser or sham treatment sessions over 3 weeks, and be followed up at months 1, 3, 6 and 12 after surgery. You will need to attend the clinic 10 times in total. Treatment sessions take approximately 15 minutes each. Follow-up assessment visits take approximately 15 minutes each.

The following is a summary of what will happen at each visit:
If you agree to take part in this study, the following will happen to you:

Visits 1-6 (weeks 1-3 post-surgery): Six laser or sham sessions, twice weekly over 3 weeks. Each session takes approximately 15 minutes.

Visits 7–10 (months 1, 3, 6 and 12 after surgery): Sensation tests and questionnaires at each visit. Each visit takes approximately 15 minutes.

When your participation in the study ends at 12 months, you will have completed all study visits. If you are in the sham group and have not yet fully recovered sensation by 12 months, you will be offered the active laser treatment at no charge through our clinic.

Sensation tests:
At each visit, the following simple painless tests will be done on your lower face and cheek area by a trained assessor:

(1) A blunt-ended needle shaft will be gently pressed against the skin to test how well you feel touch. You will be asked to rate the sensation on a scale from 0 (normal) to 10 (no sensation). (2) Small calibrated filaments (Semmes-Weinstein monofilaments) will be pressed lightly on the skin to measure the lightest touch you can feel. (3) A small two-pronged instrument (Disk-Criminator) will be placed on the skin to test whether you can tell two separate points of touch apart. No needles will pierce the skin. No blood samples will be taken.

Medical and dental records:
We will collect information from your medical and dental records relating to your jaw surgery, including your diagnosis, the type of surgery performed, and your postoperative recovery notes. This information will be used to confirm your eligibility and describe the study population.

Questionnaires:
At each assessment visit, you will complete two short questionnaires: (1) the Neuropathic Pain 4 (DN4) questionnaire (10 questions about the quality of your abnormal sensation, approximately 2 minutes); and (2) the Oral Health Impact Profile (OHIP)-14 questionnaire (14 questions about how your mouth and facial symptoms affect your daily life, approximately 3 minutes). You may skip any question you are uncomfortable answering.

4. What Happens to the Data and/or Samples Collected for the Research

Any information containing your "Personal Data" that is collected for the purposes described in this Informed Consent Form will be stored in Singapore and will not be transferred out of Singapore. Any individually-identifiable data obtained during the course of this study will be stored and analysed for the purposes of this study and will not be used for future biomedical research

5. Incidental Findings

"Incidental findings" are findings that have potential health or reproductive importance to research participants like you/your child and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study. This study involves only painless surface sensation tests and low-energy laser or sham laser treatment applied to the skin. No blood tests, imaging scans, or genetic tests are performed. There will not be any incidental findings arising from this research.

6. Your Responsibilities in This Study

If you agree to participate in this study, you should: attend all 10 scheduled visits; follow all instructions given by the study team; not start new medicines for nerve recovery (pregabalin, or gabapentin) without telling the study team; inform the study team immediately if you experience any unexpected symptoms; inform the study team if you become pregnant; and inform the study team if you wish to withdraw.

7. What Is Not Standard Care or is Experimental in This Study

This study is being conducted because photobiomodulation laser treatment has not yet been tested in a sham-controlled clinical trial for nerve recovery after jaw surgery. We are conducting this study to find out whether the treatment produces a real effect beyond placebo.

The Marcos PBM M device (Fotona Lightwalker) used in this study is a commercially available, registered photobiomodulation device. It is not a prototype. It is used at low, non-cutting energy settings specifically for this study.

The use of a sham (inactive laser), blinding (you and the assessor will not know which group you are in), and random group assignment are done only for research purposes to make sure the results are fair and unbiased.

Photobiomodulation laser treatment is not currently part of standard care after jaw surgery. This study is testing whether it should be. The sensation tests used in this study are also more detailed than standard clinical follow-up, and are being done for research purposes.

Data collection from medical record and questionnaire is done for the sole purpose of this study and not part of standard care.

8. Possible Risks and Side Effects

The laser or sham treatment and sensation tests used in this study may have the following side effects or risks:

Laser treatment (active group): You may experience mild redness (erythema) of the skin at the treated area. This occurs in 15% of the patients and usually goes away within a few hours without any treatment. You may feel mild warmth from the probe during the session. No cuts, injections, or numbing medicine are required.

Sham treatment (control group): The sham procedure does not deliver any laser energy. No skin effects or side effects are expected.

Sensation tests: The instruments used (a blunt needle shaft, calibrated filaments, and a two-point probe) are applied gently to the surface of the skin. They do not pierce or cut the skin. You may feel mild pressure but no significant pain is expected.

If you experience any unexpected symptoms after a treatment session or between visits, please contact the study team immediately using the contact details at the end of this form.

Eye safety: You and the doctor will both wear protective glasses (goggles) during every laser or sham session to protect your eyes. This is a standard safety precaution required for all laser procedures.

Questionnaires/ surveys/ interviews:
Questionnaires: Some questions ask about how your symptoms affect your daily life. You may feel slightly uncomfortable answering certain questions. You are free to skip any question you do not wish to answer.

Personal privacy and confidentiality:
Privacy: Your data will be labelled with a unique code instead of your name. There is a very small chance of a data breach, but we take all reasonable steps to protect your personal information including secure storage on NUH servers within Singapore.

9. Reproductive Risks to You and Your Partner(s)

There is no reproductive risk but if you become pregnant during this study, you must stop participating and inform the Principal Investigator immediately. Your clinical care will not be affected.

10. Possible benefits from Participating in the Study

If you are in the laser treatment group, you may experience faster and more complete recovery of sensation in your lower lip, chin, and cheek area after jaw surgery. This could shorten the period of numbness and improve your ability to speak, eat, and interact socially. Based on a similar study (Kayim et al., 2026), 90% of laser-treated patients recovered full sensation within 12 months compared to 40% of untreated patients. However, there is no guarantee you will benefit. With the laser safety protocols in place, the risks of the study include transient redness and warmth of the skin where the laser therapy was applied.

11. Alternatives to Participation

If you choose not to take part in this study, you will receive standard care for your condition. In our institution this would be no laser therapy (Photobiomodulation / Lower level laser therapy) along with routine follow-up appointments.

The benefits of routine post-operative follow-up allow your surgical team to monitor your recovery and identify any complications early. Most patients experience gradual spontaneous improvement in sensation over time without any specific intervention. The risk of standard care would be that without active intervention, nerve recovery is dependent entirely on spontaneous regeneration, which is variable and unpredictable. The is currently no proven standard treatment available to speed up nerve recovery after orthognathic surgery, and watchful waiting remains the only routinely offered option. Prolonged numbness or altered sensation can affect daily activities such as eating, speaking or even social interactions.

If you choose not to take part in this study, you will receive standard postoperative care from your surgical team at NUH. This includes routine follow-up appointments to check your recovery. There is currently no proven standard adjunctive treatment for nerve numbness after jaw surgery.

12. Costs & Payments if Participating in the Study

You will not incur any anticipated expenses as a consequence of participating in this study. If you take part in this study, the following will be provided at no charge to you: all laser or sham treatment sessions, all sensation testing assessments and instruments, and all study questionnaires. These costs will be covered by the study. Any additional visits due to the laser therapy (additional 3 visits) will be covered by the study team (Each visit $55.00/-, 3 visits: $165.00/- in total). A $40 voucher will be provided upon successful completion of the 3rd month review. Another $40 voucher will be provided upon successful completion of the 12th month review ($80.00 worth of voucher in total). The total reimbursement is up to $245.00.

13. Voluntary Participation

Your participation in this study is voluntary. You may stop participating in this study at any time. Your decision not to take part in this study or to stop your participation will not affect your medical care or any benefits to which you are entitled. If you decide to stop taking part in this study, you should tell the Principal Investigator.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you *(or your legally acceptable representative, if relevant*) will be informed in a timely manner by the Principal Investigator or his/her representative.

14. Withdrawal From Study

If you withdraw from the study, you will be asked to return any study equipment if applicable and, if willing, to complete a brief exit interview so that we can understand your reason for withdrawal. The data collected up to the point of your withdrawal will be kept and analysed.

Your doctor, the Investigator and/or the Sponsor of this study may stop your participation in the study at any time for one (1) or more of the following reasons *(*Failure to follow the instructions of the Principal Investigator and/or study staff.

- The Principal Investigator decides that continuing your participation could be harmful to your health or safety.

- Pregnancy
- You require treatment not allowed in the study.
- The study is cancelled.

15. Compensation for Injury

If you follow the directions of the study team and are physically injured as a direct result of the study procedures, the National University Hospital (NUH) will pay the reasonable medical expenses for the treatment of that injury. Payment for management of the normally expected consequences of your treatment will not be provided by NUH. NUH without legal commitment will compensate you for the injuries arising from your participation in the study without you having to prove that NUH is at fault. There are however conditions and limitations to the extent of compensation provided. You may wish to discuss this with your Principal Investigator.

By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

16. Confidentiality of Study and Medical Records

Your participation in this study will involve the collection of "Personal Data". "Personal Data" means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. This includes name, national registration identity card (NRIC), nationality, passport information, date of birth, and telephone number, medical conditions, medications, investigations and treatment history.

Information and "Personal Data" collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. To protect your identity, your Personal Data will be labelled with a unique code. The code will be used in place of your name and other information that directly and easily identifies you. The study team will keep a separate file that links your code to your Personal Data. This will be kept in a safe place with restricted access.

However, the Regulatory Agencies *(HSA)* and NHG Domain Specific Review Board and Ministry of Health will be granted direct access to all your original medical records regardless of where and whom you seek care from, to check study procedures and data, without making any of your information public. These may include data from other hospitals where you may have had medical consultations and/or procedures being carried out and the data is captured under the Next Generation Electronic Medical Records (NGEMR). Such data on NGEMR may be viewed and used if relevant to the study.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by *NUH*, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties as mentioned above. To the fullest extent permitted by applicable law, under no circumstances will *NUH* and/or its affiliates be liable for any direct, indirect, incidental, special or consequential loss or damages arising out of any data breach event.

All data collected in this study are the property of NUH. The data will be used for the purpose of this research study only. By participating in this research study, you are confirming that you have read, understood and consent to the Personal Data Protection Notification available at https://www.nuh.com.sg/personal-data-protection-act.

17. Who To Contact if You Have Questions

If you have questions about this research study, please contact the Principal Investigator: [Dr Yong Chee Weng, Consultant, Division of Oral and Maxillofacial Surgery, NUH. Email: DENCWY@NUS.EDU.SG, Phone number: 97872962..In case of any injury or adverse event, please contact the Principal Investigator using the details above, or call the NUH main line at 6779 5555.

18. Who Has Reviewed The Study

The study has been reviewed by the NHG Domain Specific Review Board (the central ethics committee) for ethics approval.

If you want an independent opinion to discuss problems and questions, obtain information and offer inputs on your rights as a research participant, you may contact the NHG Domain Specific Review Board Secretariat at 6471-3266. You can also find more information about participating in clinical research, the NHG Domain Specific Review Board and its review processes at ethics.gri.nhg.com.sg.

If you have any complaints or feedback about this research study, you may contact the Principal Investigator or the NHG Domain Specific Review Board Secretariat.

CONSENT FORM

Protocol Title:

Nd:YAG Laser Photobiomodulation for Neurosensory Recovery Following Bimaxillary Orthognathic Surgery: A Randomised Sham-Controlled Double-Blinded Clinical Trial

Principal Investigator & Contact Details:

Yong Chee Weng, Consultant, Division of Oral and Maxillofacial Surgery, National University Hospital, 9 Lower Kent Ridge Road, Singapore 119086. Dencwy@nus.edu.sg, 97872962

I voluntarily consent to take part in this research study. I have fully discussed and understood the purpose and procedures of this study. This study has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the study, and all my questions have been answered to my satisfaction. I have also been informed and understood the alternative treatments or procedures available and their possible benefits and risks.

I understand that my individually identifiable information (Personal Data) and data collected about me may be combined or linked with data from other sources, including but not limited to healthcare billing information, government administrative data and/or research data such as health, and health-related data, social data, education data, birth and death data, economic and housing data, data from disease registries and database, whether by itself or with the assistance of a data intermediary.

By participating in this research study, I confirm that I have read, understood, and consent to the NUH Personal Data Protection Notification.

_____	_____	_____
Name of Participant	Signature	Date

Witness Statement

I, the undersigned, certify that:

- I am 21 years of age or older.

- To the best of my knowledge, the participant/ the participant's legally acceptable representative signing this informed consent form has the study fully explained in a language understood by him/ her and clearly understands the nature, risks and benefits of his/ her participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant/ the participant's legally acceptable representative giving the consent.
- I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Name of Witness	Signature	Date

1. In accordance with Section 6(d) of the Human Biomedical Research Act and Regulation 25 of the Human Biomedical Research Regulations 2017, appropriate consent must be obtained in the presence of a prescribed witness who is 21 years of age or older, and has mental capacity. The witness must be present during the entire informed consent discussion, and must not be the same person taking the appropriate consent. The witness may be a member of the team carrying out the research.
2. However, if the participant/ the participant's legally acceptable representative is unable to read, and/ or sign and date on the consent form, an impartial witness should be present instead. The impartial witness should not be a member of the study team.

Investigator Statement

I, the undersigned, certify that I explained the study to the participant and to the best of my knowledge the participant signing this informed consent form clearly understands the nature, risks and benefits of his / her participation in the study.

Name of Investigator / Person administering consent	Signature	Date